# Does counselling benefit post-myocardial infarct patients in reducing anxiety/depression and enable them to make positive life style changes in comparison to a non-counselled group?

Submission date	Recruitment status	Prospectively registered
29/09/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	Results
Last Edited	Condition category	Individual participant data
21/04/2015	Circulatory System	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

Mrs E Brown

#### Contact details

The Hillingdon Hospital NHS Trust Pield Heath Road Uxbridge Hillingdon United Kingdom UB8 3NN

## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

N0388170251

# Study information

#### Scientific Title

Does counselling benefit post-myocardial infarct patients in reducing anxiety/depression and enable them to make positive life style changes in comparison to a non-counselled group?

#### **Study objectives**

Not provided at time of registration

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled study

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Quality of life

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Cardiovascular: Infarction

#### **Interventions**

Counselling vs non counselling

#### Intervention Type

Behavioural

#### Primary outcome measure

- 1. Improve quality of life of myocardial infarct patients
- 2. Comparison of HAD scores (Hospital Anxiety & Depression scale) at six-eight weeks post-discharge and 6 months
- 3. The CORE (Clinical Outcome Routine Evaluation) will also be used

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/02/2004

#### Completion date

01/01/2007

# **Eligibility**

#### Key inclusion criteria

All confirmed myocardial infarction with either an ST elevation myocardial infarctions confirmed by raised CK and SHBD and Non ST elevation myocardial infarctions confirmed by a positive Troponin T of >0.1micrograms.L-1.

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

**Not Specified** 

#### Target number of participants

6 patients in each arm

#### Key exclusion criteria

- 1. MI patients that do not fit the inclusion criteria
- 2. HAD Score at 12 weeks of below 8 and above 21 will be excluded from the study

#### Date of first enrolment

01/02/2004

#### Date of final enrolment

01/01/2007

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre The Hillingdon Hospital NHS Trust

Hillingdon

# Sponsor information

#### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

#### Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Hillingdon Hospital NHS Trust (UK)

# **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

#### Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration